Remarks

Claims 1-8 and 13-27 which are pending in the application have been rejected as follows. Claims 1-8 and 13-23 are rejected under 35 USC 112, first paragraph, for allegedly not to describe the invention as to its nature and how to make and use the same. Claims 23-27 are newly rejected under 35 USC 103(a) as being unpatentable over Rodriguez et al. (Arch. Virol. 1994) and Lubroth et al. (Vaccine 1996).

Applicants traverse the rejection for because the specification contains guidance for the person skilled in the art to ascertain the claimed invention as to its nature and how to make and use the same. Based on the specification, the skilled artisan can select the FMDV peptides from non-structural FMDV proteins which can be used in preparing a vaccine.

Unless there is reason to doubt objective truth of statements contained herein, specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding in scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling. It is well established that the PTO must have adequate support for its challenge to the credibility of applicant's statements. Only then does the burden shift to appellant to provide rebuttal evidence. In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367 (1971).

Apparently, the rejection is based on the grounds that:

"The scope of the claims are not commensurate with the enablement provided by disclosure with regard to the broad scope of "vaccine" encompassed by the claims. The specification, however, fails to provide sufficient guidance regarding the specific embodiments of the invention to be used as a vaccine with a reasonable expectation

of success. Applicants provide serum reactivity with the disclosed peptides as the basis of enabling the vaccine. From the disclosure [Applicant] merely provides experimental results that show the serum of infected animals are reactive to peptides in ELISA based assays (specification page 14, lines 1-8). Reactivity to particular peptides does not give any indication that such peptides would provide a prophylactic effect to all animals claimed."

Applicants traverse the rejection because ELISA based assays can provide some evidence (antibody stimulation) indicating that such peptides would be efficacious. The burden, therefore, falls on the Examiner to establish why the ELISA based assay would not be effective in this case. Applicants acknowledge that in evaluating recovery from viral infection, the fact that a particular cell, substance or phenomenon may be unequivocally demonstrated to produce antiviral effects in culture does not prove its importance in vivo. It is, however, a well established approach to analyze a phenomenon such as antibody production in isolation, using relatively defined reagents in vitro. Having been alerted this way, one must return to the living animal to establish the significance of the approach. Nevertheless, much has been learned by this approach of considering evidence, indicating protection against viral infection.

Claims 1-8, and 13-23 stand further rejected under 35 USC 112, first paragraph for failing to satisfy the description requirement. The premise of the rejection is that"

"The instant claims are drawn to FMDV vaccine that is based on peptide sequences of at least 8 amino acids that correspond to part-sequence from non-structural proteins of FMDV. The specification has shown linear peptides that react with antibodies in the serum from vaccinated and infected animals".

Applicants traverse the rejection because the skilled artisan can ascertain the peptide sequences of at least 8 amino acids and employ the same in vaccines. Therefore, the description requirement is satisfied.

While the foregoing is sufficient to overcome the rejection, Applicants would

submit a representative showing of the vaccine and use thereof in protecting cattle against the subject disease in order to expedite the prosecution and allowance of the claims.

As to the new rejections, it appears that said rejections should be directed to Claims 24-27. Applicants therefore, seek a clarification of the rejection in order address the same by argument or amendment.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

6. (Amended) Peptides ~~according to~~ as defined in Claim 1 which are modified by coupling to carrier proteins or inactivated viruses.